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Case No. 10546/6

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
John W. Wong et al.

U.S. Patent Application
Serial No.: 09/424,431

Filed: March 16, 2000

For: METHOD AND APPARATUS FOR DELIVERING RADIATION THERAPY DURING SUSPENDED VENTILATION

Examiner: Mendoza, M.G.

Art Unit: 3761

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Appeal is in response to the Final Office Action mailed September 8, 2003[1].

[1] Appellants filed a Notice of Appeal and a Petition for Extension of Time (one month extension) on January 8, 2004. Since Appellants are filing a Petition for one month extension of time concurrently with the filing of the present Appeal Brief, the present Appeal Brief is timely filed.

I. REAL PARTY IN INTEREST

William Beaumont Hospital is a real party of interest in this Appeal pursuant to an assignment of the above-identified application to William Beaumont Hospital by the inventors.

II. RELATED APPEALS AND INTERFERENCES

The undersigned, John C. Freeman, is not aware of any other appeals or interferences that would directly affect or be directly affected by or have a bearing on the Board's decision in the pending Appeal.

III. STATUS OF CLAIMS

The status of the claims is as follows:

Claims 1-14 and 16-22 are canceled.

Claim 15 is currently pending.

Claim 15 is finally rejected under 35 U.S.C. § 103 as being obvious in view of the combination of U.S. Patent No. 5,067,494 to Rienmueller et al., U.S. Patent No. 5,915,381 to Nord and U.S. Patent No. 6,436,127 to Anderson et al.

The rejection of claim 15 under 35 U.S.C. §103 is the subject of this Appeal.

IV. STATUS OF AMENDMENTS

Appellants have not filed any Amendment in response to the Final Office Action mailed on September 8, 2003.

V. SUMMARY OF INVENTION

An understanding of the present invention can be made upon a review of several embodiments of the invention shown in Figs. 1-3 and 5-6 of the specification. In one

embodiment shown in Fig. 1, an active breathing control apparatus 10 utilizes a ventilator assembly 13. (p. 9, ll. 5-6). The apparatus 10 has two "scissors" valves 14 and 16 to monitor and control inhalation and exhalation independently. (p. 9, ll. 7-8). During normal operation, one of the valves 14 or 16 is always closed while the other is open. (p. 9, ll. 8-10). The scissors valves 14 and 16 are interfaced to a personal computer. (p. 9, ll. 10-12). The signals from the valves 14 and 16 are processed to display the changing lung volume during the breathing cycle. (p. 9, ll. 12-13). Software allows the user to specify (1) the point in the breathing cycle for closing both valves 14 and 16, and (2) the duration of the active breath-hold. (p. 9, ll. 13-15).

As shown in Figs. 1-3, a patient 12 is interconnected to the modified ventilator assembly 13 through a subassembly 18 which includes a t-connector 19 which includes one-way valves 20 and 21, a pneumotach 22 and a mouthpiece 23. (p. 9, ll. 16-19). A tube 24 connects the scissor valve 14 and a second tube 25 connects to the other scissor valve 16. (p. 9, ll. 19-20). A nose clip 26 is used to prevent ventilation through the nose. (p. 9, ll. 20-21). Alternatively, the mouthpiece and nose clip 26 can be replaced by a face mask. (p. 9, ll. 21-22).

The valves 14 and 16 as well as the pneumotach 22 are connected to a computer 28 which selectively drives each element according to a selected operations program. (p. 10, ll. 1-3).

The approximate position of the ventilator assembly 13 relative to a supine patient 12 is shown in Fig. 2. (p. 10, ll. 4-6). A mirror 30 may be provided at an angle for viewing by the patient 12. (p. 10, ll. 6-7). A monitor 32 may be provided outside of the treatment room

for the operator, while a smaller monitor 34 (or LCD) may be provided for viewing by the patient. (p. 10, ll. 8-10). The monitors 32 and 34 continuously display the cyclical lung volume trace and the target respiration level while the supine patient is breathing. (p. 10, ll. 10-12). Each of the monitors 32 and 34 is operatively associated with the computer 28. (p. 10, ll. 13-14). An abort switch 36 may also be provided for operation by the patient 12 to turn off the radiation machine and open the valve 14 in the event of discomfort. (p. 10, ll. 14-16).

A second embodiment of the present invention is shown in Figs. 5 and 6. The apparatus 50 includes a control apparatus 50, and a single valve 52 and a pneumotach 54 to monitor and control inhalation and exhalation. (p. 10, l. 23 – p. 11, l. 2). The valve 52 and the pneumotach 54 are connected to a computer 55 via lines 56 and 58. (p. 10, ll. 2-4). The pneumotach 54 is also fluidly connected to a carbon dioxide remover 60 and a millipore filter 61. (p. 10, ll. 4-5).

When the apparatus 50 is operatively associated with a supine patient 12', the patient 12' is provided with a noseclip 26 as shown in Fig. 6. (p. 11, ll. 7-8). A mouthpiece 13' is used for ventilation. (p. 11, ll. 8-9). The fluid line 62 is connected with the millipore filter 61 via the fluid tube 62. (p. 11, 9-10). A mirror 64 may be provided at an angle for viewing by the patient 12'. (p. 11, ll. 10-11). A monitor 66 is preferably provided outside of the treatment room for the operator, while a smaller personal monitor (or LCD) 68 is optionally provided for viewing by the patient. (p. 11, ll. 11-14). Both the monitor 66 and the personal monitor 68 are operatively associated with the computer 55. (p. 11, ll. 14-15). An abort

switch 70 may also be provided for operation by the patient 12' to turn off the radiation machine and open the valve 52 in the event of discomfort. (p. 11, ll. 15-17).

Operation of the apparatuses 10 (Figs. 1-3) and 50 (Figs. 5-6) is similar. In particular, the patient lies in a supine position on a rigid surface table-top. (p. 12, ll. 3-4). Breathing through the nose is restricted by the noseclip. (p. 12, ll. 4-5). One end of the bi-directional pneumotachnometer is connected to the patient via the mouthpiece while the other is connected to the scissors valve (one or two valves, depending on the embodiment) which controls airflow. (p. 12, ll. 5-7). Airflow to and from the patient passes through a "soda lime" reservoir to remove exhaled carbon dioxide in the apparatus of the present invention. (p. 12, ll. 8-9). To ease patient burden, the patient is allowed to nose breathe after each sequence of maneuvers which takes no more than 5 minutes. (p. 12, ll. 11-13).

The apparatuses 10, 50 are calibrated for flow and volume measurements based on acceptable hospital standards. (p. 12, ll. 14-15). The output of the pneumotachnometer is interfaced with a Pentium class PC. (p. 12, ll. 15-16). The flow signal is processed to calculate the changing lung volume during breathing in real-time. (p. 12, ll. 16-18). Operation of the scissor valve(s) is done under computer control. (p. 12, ll. 18-19). Software utilities are implemented to allow the user to select the lung volume and flow direction for closing the valve(s) of the embodiments of Figs. 1-3 and 5-6. (p. 12, ll. 19-20). A separate "arming" utility is engaged and allows the user to specify a time delay for activating the system. (p. 12, ll. 20-22).

In each of the embodiments of Figs. 1-3 and 5-6, an operating reference needs to be reestablished for the patient to set the desired respiratory phase for the apparatuses 10, 50.

(p. 13, ll. 4-5). The functional residual capacity (FRC) of the lungs at the end of normal expiration is chosen because it is the most stable lung volume during normal breathing. (p. 13, ll. 5-7). At FRC, the lungs are at a natural resting position with neutral pressure. (p. 13, ll. 7-8). At the start of each session, the supine patient will first go through a period of normal breathing to establish a stable breathing pattern. (FIG. 4, p. 13, ll. 8-10). After that, the volume signals at FRC are averaged for one minute, equivalent to 12 to 15 breathing cycles, and then set as the "zero volume reference." (p. 13, ll. 10-12). With this zero reference, lung volumes at either inspiration or expiration can be specified. (p. 13, ll. 12-14).

During an initial training session using the apparatuses 10, 50 of Figs. 1-3 and 5-6, the period of active breath hold that can be comfortably maintained by each individual patient is determined. (p. 13, ll. 16-18). The period is used for subsequent CT scanning and treatment, but is adjusted as necessary. (p. 13, ll. 18-19). When the supine patient breathes in and out through the apparatuses of Figs. 1-3 and 5-6, the cyclical lung volume trace and the target level is displayed continuously on a monitor for the user outside of the treatment room. (p. 13, ll. 19-22). Inside the treatment room, the patient is shown a similar display and the countdown of the breathhold period via an angled mirror. (p. 13, ll. 22-24). The patient may also be provided with an "abort" switch to turn off the radiation machine and open the valve of the apparatus in case of discomfort. (p. 13, l. 24 – p. 14, l. 2).

A method of using the devices of FIGS. 1-3 and 5-6 is illustrated by the flow chart of Fig. 7. In a first step 100, a specific air flow direction and lung volume are identified. (p. 14, ll. 9-10). This identification is conducted with CT scans taken at different phases of suspended ventilation. (p. 14, ll. 10-11).

In a second step 200, patient ventilation is suspended at the specific air flow direction and lung volume. (p. 14, ll. 12-13). Ventilation suspension is accomplished by closing the valves. (p. 14, ll. 13-14). Radiation therapy is administered during suspension of patient ventilation per step 300. (p. 14, ll. 16-17).

VI. ISSUES

There is only one issue presented for review: whether claim 15 is obvious under 35 U.S.C. § 103 in view of the combination of U.S. Patent No. 5,067,494 to Rienmueller et al., U.S. Patent No. 5,915,381 to Nord and U.S. Patent No. 6,436,127 to Anderson et al.

VII. GROUPING OF CLAIMS

The patentability of claim 15 stands alone.

VIII. ARGUMENT

(iv) Rejection under 35 U.S.C. § 103

The Final Office Action of September 8, 2003 (hereinafter "the Final Office Action") finally rejected claim 15 under 35 U.S.C. §103(a) as being obvious in view of the combination of United States Patents Nos. 5,067,494 (Rienmueller et al.), 5,915,381 (Nord) and 6,436,127 (Anderson et al.). Petitioner traverses this rejection for several reasons. First, Anderson et al. is directed to nonanalogous art. The test for nonanalogous art is as follows:

> The determination that a reference is from nonanalogous art is therefore two-fold. First, we decide if the reference is within the field of the inventor's endeavor. If it is not, we proceed to determine whether the reference is reasonably pertinent to the particular problem with which the inventor was involved. In re Deminski, 796 F.2d 436, 230 U.S.P.Q. 313 (Fed. Cir. 1986) citing In re Wood, 559 F.2d 1032, 1036, 202 U.S.P.Q. 171, 174 (C.C.P.A. 1979).

Upon applying the first prong of the test, Anderson et al. is not within Appellants' field of endeavor. Appellants' claimed invention is in the field of methods and apparatuses for delivering radiation therapy during suspended ventilation. This is confirmed by reviewing 1) the "Field of the Invention" section of Appellants' Specification at page 1, lines 5-8 and 2) the preamble of claim 15 which recites "[a]n apparatus for suspending ventilation in a patient and delivering radiation therapy to the patient during suspended ventilation." In contrast, Anderson et al. discloses a phototherapeutic treatment for psoriasis that does not in any way include suspending ventilation of a patient. Instead, Anderson et al.'s patient 10 breathes normally and does not have his or her breathing suspended. Thus, Anderson et al. is not within Appellants' field of endeavor, delivering radiation therapy during suspended ventilation.

Besides not being within Appellants' field of endeavor, Anderson et al. is not reasonably pertinent to the particular problem with which Appellants were involved. As stated on page 3 of Appellants' Specification, the problem of organ and tumor movement during radiotherapy due to motion of the lungs and diaphragm is the concern of Appellants' claimed invention.

It is clear that Anderson et al. does not address Appellants' problem. Instead, Anderson et al. regards applying phototherapy to the skin of a patient 10 in a sufficient manner so as to achieve clearing up the psoriasis without causing painful sunburn-like reactions. (Col. 2, ll. 9-10). While Anderson et al. does disclose either using a table 12 designed to have a patient remain steady while standing (Col. 9, ll. 28-31) or a table designed to reduce patient movement while lying down (Col. 9, ll. 31-34), nowhere does Anderson et

al. disclose or suggest that lung or diaphragm movement of the patient 10 hinders the ability to determine the proper phototherapy for the skin of the patient 10. Thus, Anderson et al. fails both prongs of the test and so is directed to nonanalogous art.

In a related issue, even should Anderson et al. be deemed analogous art, it is respectfully submitted that the combination of Rienmueller et al., Nord and Anderson et al. under § 103 is improper, because of a lack of motivation to do so. In particular, Rienmueller et al. does not disclose or suggest "identifying a specific air flow direction." Instead, Rienmueller et al. discloses using a spirometer 8 that determines the magnitude of the vital capacity of the patient. (Col. 3, ll. 14-16). It is noted that the Final Office Action has relied on the following passage at column 2, lines 3-4 of Rienmueller et al. as disclosing identifying an air flow direction:

> erator. For generating the trigger signals dependent
> upon the flow of breath through the spirometer. The patient

The above passage is silent as to determining an air flow direction. If the Final Office Action is relying on the phrase "flow of breath" as implying that a direction is identified, then the Final Office Action is in error. Rienmueller et al. only discloses using sensors 11 to determining the number of times that a light path is interrupted by the rotation of a turbine 10. (Col. 3, ll. 8-11). Accordingly, nowhere does Rienmueller et al. disclose identifying an air flow direction.

Neither Nord nor Anderson et al. solve the deficiencies of Rienmueller et al. in that neither reference discloses identifying an air flow direction. Accordingly, there is no suggestion in either Nord or Anderson et al. to alter Rienmueller et al. so that it identifies an

air flow direction. Without such disclosure or suggestion, the rejection is improper and should be withdrawn.

The rejection is improper for the additional reason that there is no disclosure and suggestion in Rienmueller et al. to use an abort switch adapted to halt the apparatus for administering radiation therapy and open a closed valve. It is noted that the Final Office Action conceded that Rienmueller et al. and Nord each fail to disclose using the recited abort switch of claim 15. The Final Office Action relied on Anderson et al. as providing motivation to modify Rienmueller et al. to include the recited abort switch. Your Petitioner traverses this reliance on Anderson et al. Anderson et al. is directed to an apparatus for delivering ultraviolet radiation to discrete areas of a patient's skin. Anderson et al. is completely unrelated to any type of suspension of breathing during radiation therapy (see, for example, Figures 1 and 2). It is noted that the Final Office Action relied on a "kill switch" mentioned at column 12, lines 3-5 of Anderson et al. as providing motivation to use the recited abort switch in Rienmueller et al. However, Anderson et al.'s "kill switch" only performs the function of closing shutter 36 and terminating "delivery of therapeutic doses of radiation to the patient." (Col. 12, ll. 3-5). Anderson et al. fails to have the "kill switch" also open a closed valve that is adapted to either control inhalation or exhalation of the patient in the manner recited in claim 15. Furthermore, Anderson et al.'s shutter 36 that is controlled by the "kill switch" cannot properly be viewed as a valve adapted to control inhalation and/or exhalation of a patient. Rather, as expressly described by Anderson et al., the shutter 36 simply controls transmission of radiation to the skin of a patient by positioning "...the screen [illegible]ock the beams, or pass the beams through one of the apertures." (Col. 11, ll. 14-16).

Based on the above, the rejection of claim 15 under 35 U.S.C. § 103 is improper and should be withdrawn.

In summary, Appellants respectively submit that claim 15 is improperly rejected under 35 U.S.C. § 103, because Anderson et al. is directed to nonanalogous art and there is no suggestion in the cited art to alter Rienmueller et al. to 1) identify an air flow direction and 2) to use an abort switch adapted to halt the apparatus for administering radiation therapy and open a closed valve. Consequently, Appellants respectfully submit that the rejection should be withdrawn and that claim 15 should be allowed.

Respectfully submitted,

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IX. APPENDIX

15. An apparatus for suspending ventilation in a patient and delivering radiation therapy to the patient during suspended ventilation, the apparatus comprising:

an apparatus for identifying a specific air flow direction and lung volume of the patient;

an apparatus for suspending patient ventilation at said specific air flow direction and lung volume, said apparatus for suspending patient ventilation including a ventilator assembly having a first selectively operable valve adapted to control inhalation of the patient and a second selectively operable valve adapted to control exhalation of the patient;

an apparatus for administering radiation therapy during the suspension of patient ventilation; and

an abort switch adapted to halt the apparatus for administering radiation therapy and open a closed one of the first and second selectively operable valves.